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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,505	02/14/2005	Hisashi Narimatsu	BJS-159-86	3424

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,505	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-5,8,10,15 and 18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9,11-14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/05, 7/05, 7/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group II as it pertains to SEQ ID NO:3 and the species of SEQ ID NO:23 in the reply filed on 5/29/07 is acknowledged. The traversal is on the ground(s) that applicants believe that the subject matter of the Examiner's Groups I to V and Groups (A) to (D) relate to a single general inventive concept and have the same and corresponding special technical feature Applicants point out that the protein of Kawar et al. cited by the examiner differs from that of the instant invention in source, size, substrate specificity and sequence. This is not found persuasive because the claims are not limited to SEQ ID NO:3, polynucleotides encoding SEQ ID NO:3 etc. Applicants claims are much broader such that the protein of Kawar et al. is within the scope of proteins encompassed by Group I. As such this genera of proteins is not a special technical feature linking Groups I-V. Furthermore, with regard to the restriction between Groups (A)-(D), applicants response fails to point out what they think the special technical feature linking these groups in fact is. The polynucleotides of Groups (A)-(D) all have different structures such that they do not have any technical feature in common.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5, 8, 10, 15, and 18-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/29/07.

Claims 6, 7, 9, 11-14, 16, and 17 are objected to as dependent on a non-elected claim and as including non-elected subject matter.

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of an intended use in a compound claim carries no patentable weight. As the only distinction between claims 13 and 16 is the recitation "which is used as a cancer marker" in claim 16, claim 16 does not further limit claim 13.

Claims 7, 9, 13, 14, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 9, and 13 (upon which claims 14, 16, and 17 depend) are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While pages 18-19 of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO: 4, a sequence must be to be included within the scope of these claims.

Claim 9 is indefinite in the recitation of "a nucleotide sequence represented by nucleotides 1-2997 or the nucleic acid sequence shown in SEQ ID NO:4" as it is unclear if this is synonymous with "a nucleotide sequence comprising SEQ ID NO:4" or if SEQ ID NO:4 is just one representative member of a larger undefined group of sequences. For purposes of further examination this is presumed to be synonymous with "a nucleotide sequence comprising SEQ ID NO:4"

Claims 6, 11-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6, 11 and 12 are directed to a genus of nucleic acids encoding any protein having ß-1,4 N-acetylgalactosamine transferase activity. The specification teaches the structure of only a few representative species of such nucleic acids. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 13 and 16 are directed to a genus of nucleic acids which hybridize to a nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity.

The specification does not contain any disclosure of the function of all nucleic acids which hybridize to a nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine

transferase activity. The genus of nucleic acids that comprise these above nucleic acids is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated nucleic acids are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a few species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 6, 7, 11-13, and 16 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding the protein of SEQ ID NO:3, does not reasonably provide enablement for any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity or any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity which will hybridize to SEQ ID NO:4 under any conditions which could be considered

stringent or for any nucleic acid which will hybridize to a nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 6, 11 and 12 are so broad as to encompass any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity while claim 7 recites any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity which will hybridize to SEQ ID NO:4 under any conditions and claims 13 and 16 recite any nucleic acid which will hybridize to a nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e.

expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only 4 ß-1,4 N-acetylgalactosamine transferases.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity or any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity which will hybridize to SEQ ID NO:4 under any conditions which could be considered stringent or for any nucleic acid which will hybridize to a

nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting ß-1,4 N-acetylgalactosamine transferase activity; (B) the general tolerance of ß-1,4 N-acetylgalactosamine transferases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity or any nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity which will hybridize to SEQ ID NO:4 under any conditions which could be considered stringent or for any nucleic acid which will hybridize to a nucleic acid encoding a protein having ß-1,4 N-acetylgalactosamine transferase activity. The scope of the

claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated host cells transformed with a nucleic acid encoding SEQ ID NO:3, does not reasonably provide enablement for host cells within a multicellular organism that have been transformed with a nucleic acid encoding SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 12 is so broad as to encompass host cells transformed with specific nucleic acids, including cells in *in vitro* culture as well as cells within any multicellular organism. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of host cells broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods

for successfully transforming cells within complex multicellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within one multicellular organism are unlikely to be applicable to transformation of other types of multicellular organisms as multicellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multicellular organism for the production of polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is suggested that applicants limit the claims to "An isolated host cell …".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Isogai et al. (EP 1308459).

Isogai et al. teach a nucleic acid (SEQ ID NO : 1696 of Isogai et al.) having 99.7% identity to residues 72-2060 of SEQ ID NO:4 of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Isogai et al. (US Patent 6,943,241).

Isogai et al. teach a nucleic acid (SEQ ID NO : 1696 of Isogai et al.) having 99.7% identity to residues 72-2060 of SEQ ID NO:4 of the instant application. This nucleic acid will

clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mao et al. (WO 01/72832).

Mao et al. teach a nucleic acid (SEQ ID NO:1 of Mao et al.) having 99.6% identity to residues 1268-1781 of SEQ ID NO:4 of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AK097681.

GenBank Accession No. AK097681 teach a nucleic acid having 100% identity to residues 1616-2997 of SEQ ID NO:4 (including all of SEQ ID NO:23) of the instant application. This nucleic acid will clearly hybridize to SEQ ID NO:4 under even high stringency conditions.

Claims 6, 11, 12, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawar et al. (see IDS of 7/05).

Kawar et al. teach a nucleic acid encoding a protein with ß-1,4 N-acetylgalactosamine transferase activity, and vectors and host cells comprising said nucleic acid. Kawar et al. further teach primers for amplifying this nucleic acid which

will clearly hybridize thereto. Therefore, Kawar et al. anticipate all of claims 6, 11, 12, 13 and 16.

The information disclosure statement filed 2/14/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652